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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,073	07/30/2001	Richard O. Hilson	10004450-1	2655

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,073	HILSON ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-50,52 and 53* is/are pending in the application.

4a) Of the above claim(s) *48-50,52 and 53* is/are withdrawn from consideration.

5)☒ Claim(s) *24-27* is/are allowed.

6)☒ Claim(s) *1,4-23 and 28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 4-23 and 28-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holen (US 5,320,808) in view of MacIndoe (US 5,332,549 newly cited and applied), Iwata (US 4,495,149) and Stylli (US 5,985,214). In the patent Holen teaches a reaction cartridge and carousel for a biological analyzer. A semi-automated biological sample analyzer and subsystems are provided to simultaneously perform a plurality of enzyme immuno assays for human IgE class antibodies specific to a panel of preselected allergens in each of a plurality of biological samples. A carousel is provided to position and hold a plurality of reaction cartridges. Each reaction cartridge includes a plurality of isolated test sites formed in a two dimensional array in a solid phase binding layer contained within a reaction well which is adapted to contain a biological sample to be assayed. The carousel and cartridges contain structures cooperating to precisely position the cartridges in each of three separate dimensions so that each cartridge is positioned uniformly. An optical reader operating on a principle of diffuse reflectance is provided to read the results of the assays from each test site of each cartridge. Also provided is a subsystem which provides predetermined lot-specific assay calibration data which is useful for normalizing the results of various assays with respect to predetermined common standard values. The biological sample analyzer (10) includes a processing chamber (11) in which to test biological samples. A chamber door (12) is preferably hingedly mounted to the analyzer overlying the chamber to selectively close off and provide access thereto. Inset into the chamber

door is a translucent viewing window (14$ which allows an operator to view the activity within the processing chamber. The window preferably includes a reagent addition port (16) through which reagents can be introduced into the chamber without opening the chamber door. The processing chamber contains a holding rack, preferably in the form of a rotatable carousel (18) which holds and conveys reaction cartridges (80) in order to position the cartridges at stations to receive sample and selected reagents and for reading test results therefrom, and to provide agitation required for processing the samples. the carousel also functions as a very precise optical bench, accurately positioning each reaction cartridge relative to an optical reader (32) to facilitate accurate and repeatable reading of test results directly from the cartridges. The carousel is preferably disposed on a tilted axis. Rotation of the carousel about this tilted axis provides desirable agitation of the fluids in a reaction well (86) of each reaction cartridge thereby promoting faster and more complete reactions and allowing the use of smaller volumes of sample and reagents than has previously been possible. A wash/waste unit preferably is provided and includes chambers (22,24) for holding wash solution to be added to the reaction cartridges and waste fluid aspirated from the reaction cartridges. A wash manifold (26) functions both as a cover for the chambers and as a mount for wash tubing and waste tubing (21,23). Wash and waste fluids are caused to flow through wash and waste tubing by means of peristaltic pumps (25,27). Wash and waste fluids are preferably introduced into and removed from the reaction wells of reaction cartridges mounted on carousel by means of a fluid probe (28) which is mounted proximate the free end of a horizontal, pivotally-mounted probe arm (33). In a preferred embodiment, fluid access to a reaction cartridge is provided when the carousel conveys the reaction cartridge to a preselected wash of the biological analyzer. At this position, the tilt of the carousel causes any fluid in the reaction well to gravitate towards a corner of the reaction well for removal by aspiration with the fluid probe. The preferred reaction cartridge includes a test card (82) having an array of test sites (84) preferably in close proximity to each other. The test card is contained within a reaction well defined by a well wall (88). The reaction well is preferably provided with a removable, preferably transparent well cover (90), which preferably includes a reagent port (92) to facilitate the delivery and removal of fluids from the reaction well. The reaction cartridge also preferably includes code means (94) such as an optical bar code attached to or printed directly on a flat surface (91) of the reaction cartridge. The bar code is

adapted to be read by the optical reader or by other conventional optical reader means and includes a lot code, which is advantageously used to access stored assay calibration data corresponding to the particular reaction cartridge being tested. The test card is preferably a laminate structure comprising a binding layer (83) adhered to a non-absorbent substrate (85) using an adhesive such as a double-sided adhesive film (87). The capture reagent or assay binding components include any compound capable of directly or indirectly binding a desired component from a biological test sample. For example, a capture reagent or assay binding component may include antibodies, antigens, biotin, antibiotin, avidin, lectins, or peptide sequence probes, as well as combinations of the above (column 15 lines 9-19). The capture reagent can also be DNA for hybridization assays (column 13, lines 52-54). Columns 31-33 discuss the system control architecture of the analyzer including a bus (320). Columns 33-38 gives an explanation of the steps involved in the analysis including the manual steps of adding sample, conjugate, substrate and removing the cover. Holen is a semi-automated device and therefore requires operator intervention to place the reaction cartridge on the carousel and add fluids. As such Holen does not teach an input means or an output means or removing the cover prior to adding fluids.

In the patent MacIndoe teaches an automated analytical instrument for conducting assays for components of interest in fluid samples. The instrument includes a rotably mounted supply unit or segment adapted to hold a plurality of foil-sealed magazines containing assay modules (17), a testing system (21) for assaying a fluid sample for a component of interest using an assay module, an assay module transport assembly for transporting an assay module from a magazine in the supply unit to the testing system, and a microprocessor for controlling the operation of the automated analytical instrument. In one embodiment, the assay module transport assembly includes a cutter assembly for cutting away a layer of material such as a thin foil layer covering a desired assay module within the magazine, an assay module receiving platform disposed in front of the magazine, an assay module ejector mechanism for pushing an assay module from the magazine onto the assay module receiving platform, and an assay module transfer mechanism for moving the assay module from the assay module receiving platform to the testing system. The cutter assembly and the assay module receiving platform are movable vertically on a first elevator assembly, and the assay module ejector assembly is movable vertically on a second

elevator assembly. Column 1, lines 24-39 describe the testing system portion of known automated analytical instruments as typically including a fluid dispensing system for metering out a quantity of the fluid sample to be analyzed to an assay module, a temperature controlled chamber for holding the assay modules at the appropriate temperature to allow the reaction to take place, an analyzing system for measuring a detectable change brought about by the presence of the substance of interest in the fluid sample and some mechanism for conveying the assay module to each of the foregoing components in the proper order. Relative to the manner in which assay modules may be provided, one type of automated analytical instrument manually loaded the assay module into an assay module transfer device. Column 2, lines 20-32 teach that automated analytical instruments including an automated mechanism for transporting assay modules stored within the instrument to the testing system are desirable since they do not require an operator to manually feed assay modules, one at a time, into the testing system. As the state of the art with respect to automated analytical instruments advances there is a continuing desire for improved mechanisms for use therein including new and improved assay module transport mechanisms for transporting assay modules from an assay module supply apparatus to the test system. Columns 11-12 describe the loading of new assay modules and the unloading of used assay modules. Relative to the used assay modules, column 11, lines 58-62 teach that they ejected into a used assay module receptacle that is not shown. The paragraph bridging columns 9-10 discuss how bar code readers are used to identify the modules.

Iwata discloses an analyzing apparatus for applying samples and reagents to the surface of a reaction carrier and for optically analyzing each component contained in the various samples. The dispensing of the samples and reagents and the optical detection operation are performed by an optics/dispensing mechanism moved relative to the reaction carrier in two dimensions. The optics/dispensing mechanism is combined with a cleaning apparatus for cleansing reagents and samples from a dispensing needle by means of a rinsing agent and air ejected toward the needle. The apparatus further includes an automatic lifting mechanism for lifting and replacing a cover disposed on the reaction carrier, and is adapted to move the dispensing needle to a position over a nearby reagent/sample holder so that the needle may take up a desired reagent or sample from the holder and transfer it to the surface of the reaction carrier. The apparatus is capable of performing highly accurate analytical measurements fully

automatically and in continuous fashion. An object of the invention is to provide an optical-type automatic analyzing and measuring apparatus which enables a variety of laboratory and clinical reactions to be analyzed and measured quantitatively and qualitatively absolutely without human intervention through automated dispensing and optical analysis of samples and reagents at predetermined positions in any desired sequence. Figures 13-17 show the covers and lifting mechanism. The lifting mechanism is adapted to lift a cover provided for the purpose of preventing the evaporation of water contained in the reaction carrier which is accommodated in a vessel, and to replace the cover following the dispensing of the prescribed reagent or sample or upon the completion of an optical measurement. The lifting mechanism can even lift and transport an object other than the cover and both raise and lower the object at a predetermined location. The lifting mechanism should be secured to the optics/dispensing mechanism at a position where the lifted object, such as the cover (71), will not impede the dispensing operation or the optical measurement, and so that the positional relationship among the lifting mechanism, optical system and dispensing mechanism will be fixed at all times.

In the patent Stylli teaches systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity. The invention is also directed automated workstations that are programmably controlled to minimize processing times at each workstation and that can be integrated to minimize the processing time of the liquid samples from the start to finish of the process. Figure 4 shows one embodiment of a sample distribution module with a conveyor means (210) comprising a rotating band that runs the length of the sample distribution module platform (220) and can transport plates. A bar code reader (230) registers plates on the conveyor means. A series of liquid handlers (240) are disposed along the conveyor means. Addressable wells in four chemical plates can be simultaneously aspirated from the liquid held in the liquid handlers, and then dispensed in additional plates. Lids can be removed or replaced by the delidder/lidder (250). Proximal and distal plate stackers (260) can be used temporarily to store plates, such as chemical and sample plates, which can facilitate plate selection. The sample distribution module can be operably linked to a sample transporter at an ingress/egress junction (270). Storage of work unit, such as plates, is accomplished with a rack system. A plurality of individual storage shelves is contained in a modular hotel (301). Modular hotels are mounted on an adjustable track system and attached to

the store framework (302). The capacity of each hotel is typically about 20 to 40 shelves. The hotels are arrayed in the store in two dimensions, referred to as X and Z. Two opposing arrays of shelves are provided, with their entries on opposite sides of a central aisle (303). Traveling along the `X` axis in the central aisle is a robotic means to store and retrieve work units. The robotic means can pick and place work units in any location in the storage and retrieval module. The robotic means comprises an integrated buffer to optimize the X axis travel. This can allow for the most efficient pick or place order via a programmed sequence of retrieval commands. The robotic means can operate on a plurality of plates without returning to the center input/output location except when the integrated buffer is fully loaded. The robotic end actuator also travels in the vertical or `Y` direction. A platen device moves in the `Y` axis to obtain units of work from the shelves, and can be used as a plate retrieval means as known in the art or developed in the future. At the ingress and egress location (304) in the center of the conveyor, there is a stacking or sorting means that can stack or sort work units. For instance, at the ingress, an upstacker creates a stack, which is transferred as a group to the robotic means. These units of work are then individually placed in the shelves of the storage and retrieval module. At the egress position, a down stacker (308) to separate units of work, and a sorting means (309) reorders the work units, so that units of work are presented to a sample transporter in the exact order required. The sample transporter (310) preferably connects to the storage and retrieval module near the center at the ingress and egress location to reduce travel time. The sample transporter can comprise a conveyor to transfer work units to workstations, and unload and offload means to assist the transfer of work units from devices, via photocells, a work unit inventory system (e.g., bar codes or other system). The sample transporter is capable of moving a unit at a rapid speed from any workstation to any other random workstation. It offers flexible parallel routing, unlike robotic means that only offer serial routing. This is a distinct advantage in drug discovery applications, and it can improve the reliability and flexibility of rapid liquid processing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate input and output means into the Holen device and method such as taught by Stylli or MacIndoe because of the reduced the operator interface with the device, reduced contamination and the ability for continuous operation of the device as taught by

MacIndoe and Stylli. It would have been obvious to one of ordinary skill in the art at the time of the invention to use notoriously well known covers such as taught by Iwata and provide means to remove the covers such as taught by Iwata or Stylli because of their well known use in preventing evaporation of fluids as taught by Iwata and if one were not concerned with the sealing advantages taught by Holen. Additionally the Court has held that selection of a known material based on its suitability for the intended use is within the skill of a routineer in the art (see *In re Leshin*, 125 USPQ 416 (CCPA 1960)).

3. Claims 24-27 are allowed. The art of record fails to teach or fairly suggest the apparatus as claimed in which the input and output means have shelves that are vertically movable as claimed. while the newly cited Farber and Takekawa references do have means for moving a "shelf" vertically, these would not be directly combinable with Holen to provide an input and output means for the assay modules and thus would end up modifying the teachings of a modifying reference.

4. Applicant's arguments filed June 2, 2004 have been fully considered but they are not persuasive. First examiner points out that the substitution of the MacIndoe reference for the Panetz reference clearly provides a stronger suggestion for modifying the Holen system with input and output storage sections that are or would be considered to be in the form of shelves. Additionally the MacIndoe input means has shelves that are movable in a predetermined manner as found in the changes to claims 16 and 45. Relative to the issue of covers both Iwata and Stylli teach covers that are notoriously well known as an alternate method of covering/protecting the fluids therein. Additionally if one were not concerned with the advantages that the port in the cover of Holen provides, it would have been obvious to use the well known covers for their known use (see *In re Leshin*, 125 USPQ 416 (CCPA 1960)).

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional art shows various means for storing reaction/assay vessels/modules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 6:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist

August 3, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER